IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO WAVE 6 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE OR OTHERWISE LIMIT THE OPINIONS AND TESTIMONY OF DEFENSE EXPERT LAWRENCE LIND, M.D.

Plaintiffs respectfully request that this Court exclude or otherwise limit the opinions and testimony proffered by Defendants Ethicon, Inc. and Johnson & Johnson's expert Lawrence Lind, M.D. ("Dr. Lind"). In support of their motion, Plaintiffs state as follows:

INTRODUCTION

Dr. Lind is a board-certified gynecological and urogynecological physician and surgeon, with board certification in Obstetrics & Gynecology and a subspecialty board certification in Female Pelvic Medicine & Reconstructive Surgery. *See generally* Exhibit C (Expert Report); Exhibit D (Curriculum Vitae). Additionally, Dr. Lind is a peer-reviewer for Obstetrics & Gynecology and International Urogynecology - Exhibit D, at 3. Plaintiffs do not challenge his qualifications as such. Dr. Lind is employed at Northwell Health-Hofstra University School of Medicine. Exhibit D, at 2. Dr. Lind obtained his medical degree from Cornell University Medical College, New York, NY, and after graduation, he was an intern in Obstetrics & Gynecology at North Shore University Hospital-Cornell University Medical College followed by a Residency in Obstetrics & Gynecology, North Shore University Hospital-Cornell University

Medical College and a Fellowship in Urogynecology / Pelvic Reconstructive Surgery at Harbor / UCLA Medical Center, Torrance, CA**.** Exhibit D at 1.

Dr. Lind was approached by the defense in this matter to provide expert opinions regarding the Gynemesh, Prolift, TVT and TVT-Exact mesh devices. However, Dr. Lind, himself, admits the following:

- He's never published any peer-reviewed articles regarding Gynemesh or Prolift mesh devices. Exhibit B at 19:10-13.
- He has never been invited to give any lectures to national societies on Gynemesh or Prolift mesh. Exhibit B at 19: 14-17
- He's never held himself out to be an expert in the implantation of Gynemesh and/or Prolift mesh at any national society meeting. Exhibit B at 21:20-24.
- He's never conducted any animal research utilizing either Prolift mesh or Gynecare mesh. Exhibit B at 33:11-15
- He's never conducted, for purposes of publication, an epidemiological study utilizing either Gynemesh or Prolift mesh. Exhibit B at 33:16-24 and 34:1-7
- Ethicon has never asked him to consult on the design of a vaginal mesh. Exhibit B at 33:7-12
- Despite having finished a residency in gynecology, a fellowship in urogynecology and the years of his academic practice, he's never excised, *en toto,* a Prolift or Gynemesh mesh device. Exhibit B at 34:19-22
- Dr. Lind, offered as an expert on the use of Gynecare Gynemesh, is not aware of the fact that Johnson & Johnson agreed, in 2012, to change the product label limiting the

use of the device to the abdominal approach and, to this day, uses the devices through the vaginal approach. Exhibit B at 42:18-24 and 43:1-10.

As discussed below, Dr. Lind's expert report misstates, misquotes and/or takes data out of context from the medical articles he reviewed in preparation for writing his expert report and relies upon medical articles proven to contain biases as the bases for his opinions.

LEGAL STANDARD

"A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case." F.R.E. 702. In the context of Rule 702, "'knowledge connotes more than subjective belief or unsupported speculation." *Daubert v. Merrell Dow Pharmaceuticals, Inc*., 509 U.S. 579, 590 (1993). Trial courts must ensure that a purported expert witness "is not merely parroting the opinions of others, but that the matters upon which she will opine are clearly within her area of expertise." *Bouygues Telecom, S.A. v. Tekelec*, 472 F. Supp. 722, 730 (E.D. N.C. 2007).

If the expert is qualified, "[t]he U.S. Supreme Court [has] established a two-part test to govern the admissibility of [the] expert testimony under Rule 702—the evidence is admitted if it 'rests on a reliable foundation and is relevant.'" *Tyree v. Boston Scientific Corp*., 54 F.Supp.3d 501, 516 (S.D. W. Va. 2014) (*quoting Daubert*, 509 U.S. at 597). Although "[t]he proponent of expert testimony does not have the burden to 'prove' anything to the court," he or she must nonetheless "come forward with evidence from which the court can determine that the proffered

testimony is properly admissible." *Id*. (*quoting Md. Cas. Co. v. Therm-O-Disc, Inc*., 137 F.3d 780, 783 (4th Cir. 1998)).

The Supreme Court has provided a non-exhaustive list of factors for a judge to consider in applying F.R.E. 702: "(1) whether a theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Cooper v. Smith & Nephew, Inc*., 259 F.3d 194, 199 (4th Cir. 2001) (*citing Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999); *Daubert*, 509 U.S. at 592-94). "The inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir.1999) (*quoting Daubert*, 509 U.S. at 594-95). Even so, "'[e]xpert witnesses have the potential to be both powerful and quite misleading[;]' the [trial] court must 'ensure that any and all scientific testimony . . . is not only relevant, but reliable.'" *Tyree*, 54 F.Supp.3d at 516 (quoting *Cooper*, 259 F.3d at 199).

ARGUMENT

I. Dr. Lind's General Opinions Regarding the Safety and Efficacy of Gynemesh and Prolift Should Be Excluded or Limited.

Dr. Lind's status as an attending gynecologist and urogynecologist does not, *per se*, qualify him as an *expert* in the use of the Gynemesh and Prolift devices. As discussed above, he admits that never published any peer-reviewed articles regarding Gynemesh or Prolift mesh devices; he has never been invited by his peer to give any lectures to national societies on Gynemesh or Prolift mesh; he's never held himself out to be an expert in the implantation of Gynemesh and/or Prolift mesh at any national society meeting; he's never conducted any animal

research utilizing either Prolift mesh or Gynecare mesh; he's never conducted, for purposes of publication, an epidemiological study utilizing either Gynemesh or Prolift mesh; Ethicon, which retained him as an expert for purposes of this litigation, has never asked him to consult on the design of a vaginal mesh; he's actually never even excised a Prolift or Gynemesh mesh devices, *en toto,* despite having finished a residency in gynecology, a fellowship in urogynecology and the years of his academic practice; he's not aware of the label change for Gynecare Gynemesh limiting the use of the device to the abdominal approach and, to this day, Ethicon's designated expert uses these devices through the vaginal approach.

This lack of knowledge highlights the uncertainty in Dr. Lind's understanding of transvaginal mesh. A reliable expert opinion must be based on scientific, technical, or other specialized knowledge and not on belief or speculation, and inferences must be derived using scientific or other valid methods." *Oglesby v. General Motors Corp*., 190 F.3d 244, 250 (4th Cir.1999). Therefore, Dr. Lind cannot give general or specific opinions on how transvaginal mesh affects and interacts, contemporaneously, with the human body because he, himself, admits to not holding that education, training and experience to support his being an *expert* in the use of these surgical devices. *See Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 260 (4th Cir. 1999) (noting that the reasoning or methodology used by an expert witness as foundational support for his opinions must be "supported by adequate validation to render it trustworthy**").** Dr. Lind plainly fails to meet this standard because he has offered no validation, other than his personal opinion, to support his contention that he is an 'expert' in the use of these surgical devices.

II. Dr. Lind's Expert Report Fails To Offer Contrary Scientific Literature And Selectively Chooses His Support From The Scientific Landscape Including Articles Shown By Authoritative Authors To Be Replete With Biases.

As this Court has observed, "[a]n expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead 'selectively [chooses] his support from the scientific landscape.'" *Tyree*, 54 F. Supp. 3d at 520 (S.D.W. Va. 2014) (quoting *In re Rezulin Products Liab. Litig.*, 369 F.Supp.2d 398, 425 (S.D.N.Y. 2005) (quotations omitted)). Where, as here, the "relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable." *Id.*

Dr. Lind is not only familiar with the Cochrane Database of Systemic Review but cites Maher, et al, *Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse (Review)*, Cochrane Database of Systematic Reviews 2016, Issue 2, Art. No.: CD012079, DOI:l0.1002/14651858 on page 3 of his Expert Report. Exhibit C. Regarding the 'authorativeness' of the Cochrane Meta-Analyses and Systematic Reviews, Dr. Lind admits that he "… "*...place(s) a special emphasis on randomized control trials, systemic reviews and meta-analyses which provide* ***the highest levels of scientific evidence***." (Emphasis added) Exhibit B at 48:2-10. He admits that he's read this systematic review and is relying upon it as the basis for several of his expert opinions. Exhibit B at 48:15-14 and 49:1.

Dr. Lind writes for this court within his Expert Report, at page 54,

Q. And the paragraph that starts off with: "**The problem of high failure.**"

We read that approximately 30 percent of patients who undergo a native tissue surgical repair, other than colpocleisis, will require re-operation for re-prolapse.

Is that correct?

A. Yes.

No reference is given for this statement leading Dr. Lind to admit that, if he had submitted his expert report for publication in a peer-reviewed medical journal, "he would have to fill that in." Exhibit B at 47:11-12.

More importantly, this Cochrane Systematic Review, which Dr. Lind describes as the highest form of scientific evidence actually states that, While "...rates of repeat surgery in prolapse were lower in the mesh groups**…(Bu)t more women in the mesh group require repeat surgery for combined outcome of prolapse, stress incontinence, or mesh**." Exhibit 8 to Lind Deposition (Exhibit B) at page 2.

Q. There is a statistically

56

significant 104 percent increased risk of repeat surgery for combined outcome of prolapse, stress incontinence, or mesh exposure.

Is that correct?

A. Yes.

Q. And that's stated in this systemic review which you described as one of the highest levels of scientific evidence, correct?

A. Correct.

Exhibit B, 55:24 and 56:1-11

On page 8 of Dr. Lind's Expert report, he lists the heading "VI. "Evidence From the Scientific Literature." Exhibit C at 8. In this section he devotes two large, full paragraphs to an article titled, '*Trocar-Guided Mesh Compared With Conventional Vaginal Repair in Recurrent Prolapse*' by Withagen et al, (Withagen) marked as Exhibit 12 to his deposition. Exhibit B at 78.

When Dr. Lind's attention was directed to page 246 and Table 1 of the 'Withagen' article, it was noted that there were 3 times as many patients in the mesh group with a pre-existing sacrocoplexy as compared to those patients in the 'native tissue' cohort. Exhibit B at 81:5-8.

12 Q. Does that indicate to you there
13 was a significantly significant larger
14 number of patients that have previously
15 had vaginal -- excuse me. Had
16 sacrocolpopexy in the vaginal mesh group
17 than in the conventional group?
18 A. Yes.

Exhibit B at 81:12-18

While not admitting that this was a source of 'bias', Dr. Lind testified,

24 Q. And that's a source of bias, is

82

1 it not?
2 A. The study is randomized, which
3 as we both know is best designed to
4 minimize bias. Despite randomization, in
5 this study you have more people in one
6 group with a previous sacrocolpopexy than
7 the other.

Exhibit B at 81:24 and 82:1-7.

Dr. Lind had already defined 'bias' as follows:

12 Q. And for whomever may be reading
13 the record, can you define "bias"?
14 A. Bias is anything that would
15 influence a study to take away from the
16 objectivity of the outcomes.

Exhibit B at 23:12-16 (Emphasis added)

Dr. Lind's attention was redirected to the Cochrane Systematic Review by Maher et al (2016), *Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse*

(Review), and page 14 where Maher et al reported on this very article by Withagen et al upon which Dr. Lind was relying as the bases of several of his expert opinions,

Q. (Reading) "We rated 18 studies that did not describe an adequate method of allocation concealment as at unclear risk in this domain, and we rated two studies as at high risk of bias, as they either did not use allocation concealment, in Tamanini 2014, **or we suspected a high potential for bias (Withagen 2011.)"**

Did I read that correctly?

A. Yes.

Q. **And the Withagen 2011 is what we**

were reading, correct?

A. Correct.

Q. Now, looking at the same page of that Cochrane analysis, you see they also have a paragraph titled "**Selective Reporting**"?

A. Yes.

Q. And there at the bottom the final sentence of that: "**We rated one study as at high risk of selective reporting because the choice of primary outcome appeared to be inconsistent (Withagen 2011).**"

Did I read that correctly?

A. Yes.

Q. And then if you look on the same page there's a section titled "**Other**

Potential Sources of Bias." And then you see in the middle of that paragraph they write: "**In Withagen 2011, women in the native tissue group had greater degree prolapse at point A posterior (Ap), point B posterior (Bp), and genital hiatus (GH) compared to the mesh group and prior**

87

sacrocolpopexy was three times more frequent in the mesh group."

Did I read that correctly?

A. Yes.

Q. So these biases in Withagen are listed in the Maher systemic review that you describe as the highest evidence of scientific -- highest degree of scientific evidence; is that correct?

A. It is a -- it is in the category of the highest level, but we are microdissecting one analysis with Withagen. That is not the study in total.

Exhibit B at 85:14-24, 86:1-24; 87:1-13 (Emphasis added)

In an attempt to alleviate Dr. Lind's concern that the Maher Cochrane Review as being 'cherry picked' for this language, his attention was directed to page 13 of the Maher Cochrane Review and '**Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study'**.

Q. The first column which they title as "Random Consequence Generation (selection bias)."

A. Right.

Q. For Withagen it's green. It gets a plus.
A. Right.
Q. Now, next to it is "**Allocation Concealment (selection bias)." That's red with negative.**
A. Okay.
Q. After that "**Blinding of**

Participants and Personnel (performance bias)." That's red.
A. Got it.
Q. "**Blinding of Outcome Assessment (detection bias),"** and that's red.
A. Got it.
Q. Then comes a yellow with a question mark, and that column is "**Incomplete Outcome Data (attrition bias)."** And then the second to last is red "**Selective Reporting (reporting bias)."** And then the final column also red is "**Other Biases."**

So, in this table alone, aside from the colpopexy bias that you discuss, **the Cochrane Review indicates the Withagen article has a minimum of five forms of bias, selection bias, performance bias**, **detection bias, reporting bias, other bias**, which I will give you may include your argument regarding colpopexy.

Now, you indicated you read the

23 Cochrane analysis in its entirety,
24 correct?

92

1 A. Almost its entirety.
2 Q. **Did you not see this section on**
3 **Withagen?**
4 A. **I saw the section on Withagen**.
5 Q. And is there any language in
6 your expert report in those two paragraphs
7 of Withagen indicating that this study
8 does in fact contain five forms of bias?
9 A. **No, there is not**.

Exhibit B at 90:13-24; 91:1-14; 92:1-9. (Emphasis added)

Therefore, Dr. Lind read both the Withagen article and the Maher Cochrane Systematic Review, the provides "…the highest levels of scientific evidence" and deliberately chose to (1) rely upon a study replete with biases and (2) failed to share with this court that the Withagen study was so biased as to not be included for analysis by Maher et al in their Systematic review.

Furthermore, Dr. Lind, on page 11 of his Expert Report (Exhibit C) relies upon an article titled 'Graft and Mesh Use in Transvaginal Prolapse Repair' by Schimpf et al. Again, no reference is provided for this article but ascertained to be Schimpf et al, *Graft and Mesh Use in Transvaginal Prolapse Repair A Systematic Review*, Obstet & Gynecol, 128;1. July 2016) (Lind Deposition, Exhibit B, Exhibit 14).

19 Q. Now, if you turn to the next
20 page, you see "Outcomes and Anterior
21 Compartments"?
22 A. Yes.

Q. At the bottom of the paragraph they write: "**20 studies compared**

98

synthetic non-absorbable mesh and native tissue repair and 11 studies compared a graft or mesh or other graft material."

Did I read that correctly?

A. Yes.

Q. **Then there's an appendix 3 link for that.**

Did you pull the link and look at those 20 studies?

A. No.

Q. **Do you know which mesh were included in those 20 studies**?

A. **No.**

Q. **Do you know how many of them consisted of Gynemesh or Prolift?**

A. **What fraction, no.**

Exhibit B at 97:19-24 and 98:1-16

However, examination of Appendix 3 from this Schimpf, in fact, reveals that just one of the 20 studies involved Gynemesh while three studes involved Prolift but not one of the studies had a follow-up of more than 12 months. Twelve of these studies which Dr. Lind is relying upon as one of the basis for his expert opinions did not even involve Gynemesh or Prolift mesh.

Further evidence of the lack of 'clarity' within Dr. Lind's Expert Report involves his reliance upon "Governing Board Committee Opinions and Guideline Statements". Exhibit C at 12. Therein, Dr. Lind writes for this court,

> *"In 2011, in a Committee Opinion published jointly between ACOG and AUGS, the* ***relative merits and risks are described for both native tissue repairs and mesh augmented repairs****. The position statement was created after the knowledge that the FDA had issued public health notifications related to vaginal mesh in 2008 and 2011. The Committee opinion does not suggest banning the use of vaginal mesh, nor does it state that there is 'no role' for vaginal mesh, but instead provides guidelines for selecting patients for vaginal mesh and consideration of such factors as recurrence of prolapse and medical comorbidities that preclude more invasive and lengthier open and endoscopic procedures. The Opinion further states that, "The approach to the repair of POP should take into account the patient's medical and surgical history, severity of prolapse, and patient preference after education regarding the benefits and risks of the surgical and nonsurgical alternatives." (ACOG Committee Opinion #513, December 2011.)"*

Exhibit C at 12.

While Dr. Lind had an understanding that 'ACOG' had a website, he did not know that the 'College' had pulled this statement 'down' off of the web. Exhibit B at 101:11-14. In addition, he did not know that this statement had been withdrawn from the Journal of Obstetrics and Gynecology. Exhibit B 101:7-10. The American College of Obstetricians and Gynecologists Women's Health Care Physicians document withdrawal was marked as Exhibit 16 to Dr. Lind's deposition transcript, Exhibit B.

Dr. Lind did *not* share with the court in his expert report that, in fact, a January 6, 2016 Advisory Statement, "ACOG Practice Advisory on the FDA's Reclassification of Mesh For Pelvic Organ Prolapse" had been issued and was marked as Exhibit 17 to his deposition transcript.

9 Q. And you would agree that 2016,
10 sir, is after 2011, correct?
11 A. Yes.
12 Q. And in this practice advisory
13 dated January 6, 2016 on point number 1
14 they write: "**The FDA reclassified these**

medical devices from Class 2, which generally includes moderate-risk devices, to Class 3, which generally includes high risk devices."

Did I read that correctly?

A. Yes.

Q. Now, while mentioning the ACOG committee opinion from 2011 in your expert report, you do not mention in your expert report that ACOG in 2016 notes that these

106

medical devices are now considered high risk devices, do you?

MS. GERSTEL: Object to form.

A. I have to look a little more through my statement because I think I do reference FDA notifications on devices.

ll101117, (Page 106:7 to 106:12)

106

Q. I'll represent to you that you do mention the 2008-2011 advisory, but nothing about --

A. **Correct, I do not -- I do not**

Exhibit B at 105:9-24 and 106:1-10. (Emphasis added)

Further evidence of Dr. Lind's failure to cite contrary opinions while providing to this Court incomplete evidence can be found on pages 14 and 15 of his expert report wherein he writes:

> "As discussed above, mesh exposure has been reported in Prolift patients in the peer-reviewed medical literature, including in randomized controlled trials, but the majority of exposures can be treated conservatively, whether expectantly or

> with topical estrogen cream, or with a minor excision that can be performed under local anesthesia in the office or in an outpatient setting. A minority of exposures must be treated surgically under general anesthesia. My own experience with patients is consistent with the results reported in the scientific literature."
> Exhibit C at 14 and 15.

Dr. Lind, in his Expert Report, fails to mention the findings from a study published by Abbott et al titled, '*Evaluation and Management of Complications From Synthetic Mesh After Pelvic Reconstructive Surgery: A Multicenter Study'*, marked as Exhibit 18 of his Deposition, Exhibit B. This study by Abbott et al is in both Dr. Lind's General and Supplemental Reliance Lists. Exhibits E and F.

As described within the abstract to this study, Abbott et al write, "*We conducted a multicenter, retrospective analysis of women who attended four U.S. tertiary referral centers for evaluation of mesh-related complications after surgery for SUI and/or POP from January 2006 to December 2010*.

On page 163.E6 of this multi-center study, including authors from the Cleveland clinic, write,

"**Of the women who initially had in-office trimming of mesh, 73.3 percent eventually went to the operating room**."

Did you see that, sir?

A. Yes.

Q. Now, again **your expert report states the majority of exposures can be treated conservatively**, whether expectantly or with topical estrogen cream, but these surgeons from these four medical centers found that 73.3 percent of these patients who undergo an in-office trimming ended up in the operating room, did they not?

A. The statements as they've written statistically and their results

23 clearly are accurate. **These are expert**
24 researchers and expert surgeons.
Exhibit B at 112:7-14

"Expert researchers and expert surgeons", as compared to Dr. Lind.

Furthermore,
19 Q. If you would turn to page 163.E6
20 they have a section there called
21 "Comment."
22 Do you see the "Comment"
23 section?
24 A. Yes.

118

1 Q. About five or six lines down
2 they start "First."
3 Do you see that?
4 A. Yes.
5 Q. (Reading) "First, approximately
6 one-half of the women (49.3 percent) who
7 sought treatment of a mesh related
8 complication at a tertiary referral center
9 actually underwent their index procedure
10 at a facility other than that tertiary
11 referral center."
12 And that's what you've been
13 saying, correct?
14 A. Yes.
15 Q. (Reading) "This trend has been
16 reported in other studies as well.
17 Reference 12. **This raises the potential**
18 concern that physicians who perform these

mesh procedures may not be aware of the complications their patients experience and that these providers may be responsible for future mesh related complications with no awareness of the existing magnitude of the issue."

119

Did I read that correctly?

A. Yes.

ll101117, (Pages 119:3 to 120:22)

119

Q. Now, the impetus for this entire line of questioning is you wrote in your expert report that mesh complications are typically mild and can be treated expectantly, mesh erosion can be treated expectantly and/or with estrogen cream, but you don't put in your expert report that there is a portion of women with the same complications that undergo very significant morbidity and surgical correction, correct?

MS. GERSTEL: Object to form.

A. I think I do indicate in my report that people do require surgery to correct this. **How detailed I get into on how invasive the repairs are is not detailed as specifically as the line of questioning here. That's fair.**

These outright errors, misstatements, reliance on objectively-proven biased studies, relying upon a study of "20 studies", 16 of which do not even involve a Gynemesh or Prolift mesh, reliance upon a statement from the American College of Obstetrics and gynecology which has been pulled down off the 'web' and withdrawn from a medical journal and his disagreement with "expert researchers and surgeons" renders Dr. Lind's testimony unreliable and inadmissible because it rests on inaccurate and misleading information. Dr. Lind did not use a reliable methodology in forming his opinions in his expert report. Dr. Lind failed to give a convincing story that he relied on more than his own beliefs. "Courts widely agree that 'trial judges may evaluate the data offered to support an expert's bottom-line opinions to determine if that data provides adequate support to mark the expert's testimony as reliable.'" *E.E.O.C.*, 778 F.3d at 472 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). It is evident here that Dr. Lind's evidentiary and supporting data does not reach the standard level of reliability necessary to render this testimony valid.

On these grounds, Dr. Lind's opinions and testimony should be excluded because they lack any and all foundation in sound reasoning and understanding.

CONCLUSION

Due to the foregoing, Plaintiffs respectfully request that this Court grant their motion and exclude or otherwise limit the opinions and testimony of Dr. Lind. Plaintiffs further request all other relief to which they are entitled.

Respectfully submitted,

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Dated: October 23, 2017